



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-4467]

Breast Implants--Certain Labeling Recommendations to Improve Patient Communication; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Breast Implants--Certain Labeling Recommendations to Improve Patient Communication." This draft guidance contains recommendations concerning the content and format for certain labeling information for saline and silicone gel-filled breast implants. FDA is seeking comments on all aspects of the draft guidance, including the respective benefits and risks of smooth and textured breast implants and applicability of the recommendations to both types. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-4467 for "Breast Implants--Certain Labeling Recommendations to Improve Patient Communication."

Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Breast Implants--Certain Labeling Recommendations to Improve Patient Communication" to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Cynthia Chang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4646, Silver Spring, MD 20993-0002, 301-796-6891.

SUPPLEMENTARY INFORMATION:

I. Background

Over the past few years, FDA has received new information pertaining to risks associated with breast implants, including breast implant-associated anaplastic large cell lymphoma and systemic symptoms commonly referred to as breast implant illness that some patients attribute to their implants. FDA has taken several steps to better understand and address risks associated with breast implants, including convening the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee on March 25-26, 2019, to discuss the long-term benefits and risks of breast implants indicated for breast augmentation and reconstruction. FDA learned

from presentations at the March 2019 panel meeting, and through comments submitted to the associated public docket, that some patients may not be receiving or understanding important information regarding the benefits and risks of breast implants in a format that allows them to make a well-informed decision about whether or not to have a breast implantation.

For these reasons, FDA is now providing recommendations concerning the content and format of certain labeling information for these devices. Specifically, FDA is recommending that manufacturers incorporate a boxed warning and a patient decision checklist into the labeling for these devices to better ensure certain information is received and understood by patients. This draft guidance also recommends updated and additional labeling information, including updates to the silicone gel-filled breast implant rupture screening recommendations, inclusion of an easy-to-find description of materials, and provision of patient device cards that were recommended at the March 2019 panel meeting.

This draft guidance is not intended to include a complete listing of all labeling components for breast implants. When finalized, the recommendations in this draft guidance will supplement or in some cases replace recommendations in FDA's guidance entitled "Saline, Silicone Gel, and Alternative Breast Implants" (November 2006) (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/saline-silicone-gel-and-alternative-breast-implants>).

Based on the information presented at the March 2019 panel meeting, FDA continues to gather available information regarding the benefits and risks associated with different types of breast implants, and consider appropriate labeling and regulatory requirements for them. FDA will continue to analyze all available information regarding the risks associated with breast implants and take additional actions as determined necessary or appropriate. FDA invites

comments on the benefits and risks of smooth and textured breast implants, respectively, as well as the labeling recommendations for these implants.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Breast Implants--Certain Labeling Recommendations to Improve Patient Communication." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. This guidance document is also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Breast Implants--Certain Labeling Recommendations to Improve Patient Communication" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 19021 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of

information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
814, subparts A through E	Premarket approval	0910-0231
812	Investigational Device Exemption	0910-0078
801	Medical Device Labeling Regulations	0910-0485
50, 56	Protection of Human Subjects: Informed Consent; Institutional Review Boards	0910-0755
830	Unique Device Identification System	0910-0720
820	Current Good Manufacturing Practice (CGMP); Quality System Regulation	0910-0073

Dated: October 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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